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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,658	07/22/2002	Alvin Berger	112843-044	6858

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EXAMINER

BERKO, RETFORD O

ART UNIT PAPER NUMBER

1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/089,658

Applicant(s)

BERGER ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**Acknowledgement:** The Amendment filed 3/21/05 is acknowledged.

#### **Status of Claims**

Applicant cancelled claim 2. Claims 1 and 3-25 remain for examination.

#### **Joint Inventors**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

#### **Claim Rejections, 35 USC 112**

Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 recites the limitation "a composition according to claim 2 wherein the precursor comprises a molecule having a plurality of formula X" in lines 1-2. There is no antecedent basis.

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Claim 4 recites the limitation a composition according to claim 2 wherein a precursor comprises a molecule having from 1 to 3 copies of formula X” in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no antecedent basis.

### **Claim Rejections-Sec 102**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. The rejection of claims 1 and 5 under 35 U.S.C. 102(b) as being anticipated by Mechoulam et al (US 5, 618, 955) is maintained.

Mechoulam et al (Patent ‘955) teaches a composition comprising arachidonyletanolamide (anandamide) and derivatives--col 4, lin 1-15; (see abstract, col3, lin 60-65, col 7, lin 65 and col 10, lin 10-15). The claims are directed toward composition for oral administration. As in applicant’s claims, Mechoulam et al teaches dosage forms of the composition for oral administration (col 5, lin 20).

Claims 1-2 and 5 are anticipated by Patent ‘955.

2. The rejection of claims 1, 5, 16, 22 and 25 under 35 U.S.C. 102(b) as being anticipated by Stordy et al (WO 96/37200) is maintained.

Stordy et al (WO ‘200) teaches a method of treating dyslexia, said method comprising administration of a pharmaceutical composition comprising docosahexanoic acid (abstract, page 1-2 and page 6).

Claims 1, 5, 16, 22 and 25 are anticipated by Patent WO ‘200.

### **Claim Rejections - 35 USC § 103**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1 and 5 and 14-25 as unpatentable under 35 U.S.C. 103(a) over Mechoulam et al (US 5, 618, 955) in view of Stordy et al (WO 96/37200) further in view of the combination et al Makriyannis et al (US 5, 874, 459) and Kyle et al (WO 94/28913) is maintained.

Mechoulam (Patent '955) disclose a pharmaceutical composition comprising arachidonyletanolamide (anandamide) and derivatives (see abstract, col3, lin 60-65, col 7, lin 65 and col 10, lin 10-15)-- see abstract, col3, lin 60-65, col 7, lin 65 and col 10, lin 10-15. Mechoulam discloses the biological activity of anadamide such as antiemetic and antiglucoma activity and other ailments (abstract; col 3, lin 35-50 and col 4, lin 30-60).

Mechoulam does not teach a method of producing a nutritional or therapeutic composition comprising docosahexanoate or anandamide from naturally occurring source and does not teach a method of treating a patient with the composition to alleviate an ailment.

Stordy et al (WO '200) disclose a method of treating dyslexia using DHA (abstract, page 1 and page 2). According to Stordy, DHA is particularly important in the function of retinal rods and that DHA significantly improves dark adaptation, reading ability and behaviour in children (page 2, and page 3); however, Stordy provides no indication of whether the compound reacts with the CB recptors.

Makriyannis et al (Patent '459) disclose novel inhibitors of anandamide amidase, said inhibitors react with CB1 and CB2 receptors (abstract, col 2, lin 15-20 and col 7, lin 45-50).

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Patent '459 discloses that a therapeutically effective amount of the anandamide amidase inhibitors is also an amount that results in a sufficiently high level of anandamide in an individual to cause physiological effects that result in stimulation of the CB receptors, thus stimulating other biological effects such as decreased nausea resulting from chemotherapy, sedation and increased appetite as well as relieving intra-ocular pressure in glaucoma patients (col 5, lin 60-65, continuing to col 6, lin 1-5).

Kyle et al (WO '913) disclose the outstanding limitation in that Kyle et al disclose a method of treating patients suffering from neuro-degenerative ailments associated with DHA or arachidonate (ARA) deficiency (abstract and page 6 lin 1--30, continuing to page 7, lin 1-5). More importantly, Patent '317 discloses preparation of DHA and ARA oils from natural sources and extracting such compounds from the biomass of cultivated microorganisms (page 8, lin 25 and page 21, lin 5-10). According to Kyle et al, the administration of DHA and ARA offer significant advantage over merely obtaining linolenic or linoleic acid from standard foods (page 25, lin 32).

One of ordinary skill would have been motivated to prepare a composition comprising DHA and ARA for administration to patients as disclosed by the prior art cited. One of ordinary skill would expect to alleviate symptoms of neuro-degenerative diseases in patients because Patent '459 has disclosed that effective amounts of long chain fatty acids that interact with CB receptors also intraocular pressure in glaucoma, stimulate analgesia and elicit anti-emetic activity by reacting with CB1 and CB2 receptors (Patent '459, col 5, lin 60-65, continuing to col 6, lin 1-5). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

### **Response To Arguments**

Applicant's arguments and remarks have been considered but are found unpersuasive:

Applicant argues that despite the fact that the compounds disclosed in Mechoulam are polyunsaturated fatty acid amides, mimic naturally occurring anandamides in the brain and bind cannabinoid receptors and also have useful physiological activity, the compounds are, unlike the instant claims, are not used as active compounds in nutritional composition.

In response, independent claim 1 is directed toward a composition for oral administration comprising naturally occurring precursor metabolized to a compound having anandamide activity. The claim is in essence drawn toward unidentified, non-existent precursor in a composition for oral administration. While examiner cannot search for an unidentified precursor compound, examiner takes the position that the disclosure in Mechoulam meets the instant claims because the compounds are anandamide related compounds shown to have physiological activity mimicking endogenous compounds in the brain(col 7, lin 65, continuing to col 8, lin 1-5). Moreover, Mechoulam discloses that the composition formed with the compound is for oral administration (col 5, lin 20).

Applicant argues lack of motivation to combine and contends that Makriyannis is directed to a method for inhibiting anandamide amidase, that Makriyannis fails to disclose or suggest derivatives of polyunsaturated acids being used as active compounds according to the claimed invention and that Makriyannis relates to a completely different objective because the compounds specified therein are compounds capable of inhibiting the degradation of anandamide by inhibiting the enzyme anandamide amidase.

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In response, examiner explained the basis for combining the references in the Sec 103 obviousness rejection, supra. Moreover, applicant is interpreting the disclosures in Makriyannis from only one perspective—the inhibition of amidase enzyme. In broader context however, one aspect of the disclosure in Makriyannis shows that inhibition of the anandamide amidase results in increased levels of anandamide in the individual (col 3, lin 40) and high levels of anandamide causes a physiological effect resulting from stimulation of cannabinoid receptors including analgesia, decreased nausea, sedation and increased appetite. Therefore, the total picture must be considered when one is looking at the physiological effects of compounds and this approach, when taken into account, provided the basis for examiner to make and maintain the Sec 103 obviousness rejection.

### Conclusion

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NEIL S. LEVY  
PRIMARY EXAMINER